UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION _____ **THIS DOCUMENT RELATES TO WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE PEGGY PENCE, PH.D.

Ethicon, Inc.; Ethicon, LLC; and Johnson & Johnson (collectively, "Ethicon") request that the testimony of Peggy Pence, Ph.D., be excluded in its entirety.

I. INTRODUCTION

Plaintiffs' regulatory expert, Dr. Peggy Pence, is now familiar to the Court. She has a bachelor's degree in microbiology from Louisiana Polytechnic University and a Ph.D. in toxicology with a minor in pharmacology; her consulting company advises other companies on dealing with the FDA. *See* Pence CV, Ex. 2 to PROSIMA Report, Ex. E. She is offered as a purported expert in the area of regulatory compliance.

In Wave 3, Dr. Pence offers general opinions regarding the TVT, TVT-O, Prolift, and PROSIMA products. The cases to which these opinions apply are listed in Ex. A.[1] Dr. Pence enumerates the following opinions, which are improper and should be excluded:

[1] Plaintiffs' designation states that they recognize the Fourth Circuit's affirmance of this Court's exclusion of evidence of compliance with the 510(k) process and "reserve the right to designate" Dr. Pence "[i]n the event of a contrary ruling." Ex. L, Pls. General Expert Desig., p. 4. Ethicon understands this to mean that Dr. Pence is not designated at all if no FDA evidence is admitted, even though this is potentially inconsistent with Dr. Pence's current disclaimer of reliance on FDA regulations. In addition, Ethicon notes that this "reservation of right to designate" in some instances puts Plaintiffs' number of experts over the allotted five.

1. **<u>As to each device (TVT, TVT-O, Prolift, and PROSIMA):</u>**

    a. That the device was misbranded due to failure to warn and false or misleading labeling. *See* Ex. B, Prolift Report, p. 106; Ex. C, TVT-O Report, pp. 103, 112; Ex. D, TVT Report, pp. 84, 89; Ex. E, PROSIMA Report, p. 42 (stating that the labeling was "inadequate" rather than using the term "misbranded"); *see also* Ex. F, Supplemental Report for TVT and TVT-O; Ex. G, Supplemental Report for Prolift and PROSIMA. ***See* Section II.B, *infra*.**

2. **<u>As to TVT, TVT-O, and Prolift:</u>**

    a. That the device was misbranded due to failure to meet the postmarket vigilance standard of care. *See* Ex. B, Prolift Report, p. 107; Ex. C, TVT-O Report, p. 133; Ex. D, TVT Report, p. 108. ***See* Section II.C, *infra*.**

3. **<u>As to TVT, TVT-O, and PROSIMA:</u>**

    a. That Ethicon failed to conduct appropriate testing of the device. Ex. C, TVT-O Report, p. 58; Ex. D, TVT Report, p. 53; Ex. E, PROSIMA Report, p. 34. ***See* Section II.D, *infra*.**

4. **<u>As to TVT-O and PROSIMA:</u>**

    a. That the device labeling was inadequate and thus did not support adequate consenting of patients. *See* Ex. C, TVT-O Report, p. 104; Ex. E, PROSIMA Report, pp. 42-43. ***See* Section II.E, *infra*.**

5. **<u>As to PROSIMA only:</u>**

    a. That Ethicon obtained clearance to market PROSIMA based on false and misleading information and misrepresentations to the FDA. Ex. E, PROSIMA Report, pp. 33-34. ***See* Section II.F, *infra*.**

    b. That Ethicon failed to act first in the interest of patient safety when it decided to remove PROSIMA from the market. Ex. E, PROSIMA Report, p. 48. ***See* Section II.G, *infra*.**

6. **<u>As to Prolift only:</u>**

    a. That the Prolift was misbranded or adulterated because it was marketed without clearance. *See* Ex. B, Prolift Report, p. 105-06. ***See* Section II.H, *infra*.**

    b. That Ethicon reported false and misleading information to the FDA. *See* Ex. B, Prolift Report, p. 106. ***See* Section II.I, *infra*.**

Three of these eight areas of testimony were addressed in this Court's Wave 1 *Daubert* rulings on Dr. Pence. *See In re: Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493685 (S.D. W. Va. Aug. 25, 2016). Ethicon requests that the Court exclude each of these areas of testimony here. In addition, Dr. Pence should be barred from offering testimony regarding products for

which she has not proffered an expert report. ***See* Section II.J, *infra*.**

II. ARGUMENT

A. Legal standard for admissibility of expert testimony.

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014); *see also* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579, 589 (1993). Applying those standards here, each of Dr. Pence's opinions should be excluded.

B. Dr. Pence should not be permitted to testify that the TVT, TVT-O, Prolift, and PROSIMA labeling was inadequate or that the devices were misbranded (TVT Report Opinion #2 and Opinion #3; TVT-O Report Opinion #2 and Opinion #4; Prolift Report Opinion #3; Prosima Report Opinion #3).

Dr. Pence is not qualified to opine about the adequacy of the IFU because she has no expertise or knowledge as to what the foreseeable user of the device already knows about what the risks of surgery using the device are. *See* Fed. R. Evid. 702. In addition to the fact that she is unqualified, Dr. Pence's opinions concerning the adequacy of the products' warnings are unreliable and inadmissible because she applies an incorrect legal standard.

1. Dr. Pence's methodology is inherently flawed because applies the wrong legal standard.

In each of these cases, Dr. Pence opines that the labels were inadequate, and she lists a myriad of risks she claims should have been included in the IFUs but were not. *See* Ex. B, Prolift Report, p. 106; Ex. C, TVT-O Report, pp. 103, 112; Ex. D, TVT Report, pp. 84, 89; Ex. E, PROSIMA Report, p. 42 (stating that the labeling was "inadequate" rather than using the term "misbranded"). Her opinions all suffer from a fatal flaw in methodology because she does not take into account what was already known by the physicians to be warned. In fact, she erroneously claims that this information was irrelevant.

In Wave 1, the Court denied Ethicon's motion to exclude this opinion, characterizing

Ethicon's argument as that Dr. Pence's testimony was unreliable "because she never spoke to any physicians about labeling and their knowledge." *In re: Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493685, at *3. Respectfully, Ethicon's argument was not simply that Dr. Pence did not speak to physicians, but rather, that she declared physicians' knowledge ***irrelevant*** to what should be in the IFU. Not speaking to physicians was just one example of how Dr. Pence did not seek to learn what physicians knew. Dr. Pence has applied an incorrect legal standard, which renders her methodology unreliable.

In her deposition, Dr. Pence was clear that physician knowledge does not factor into her analysis of the warnings' adequacy:

> Q. All right. Have you conducted any study or survey of surgeons trained in surgical treatment of SUI who implanted TVT-O to determine what risks of the TVT-O they understood from reading medical literature as opposed to reading the IFU?
>
> A. No, I haven't, and ***it's not relevant to my opinion as to what should go into the IFU. My opinion would be the same*** regardless of what the answer to any of those surveys would be because, again, the IFU is the primary communication between the doctor and the surgeon -- I mean, between the company and the surgeon.

Ex. H, Pence Dep. 3/24/16 Tr. 193:5-20 (counsel objection omitted).

Dr. Pence's standard conflicts with the state law the jury will apply and conflicts with FDA regulations she purports to interpret.

It is axiomatic in product liability law that there is no duty to warn of dangers which are obvious to consumers of a product. As one treatise puts it, if "unavoidable dangers are known or obvious, the consumer is already warned by her knowledge so that reasonable care does not ordinarily require the manufacturer to provide a separate warning." D. Dobbs, P. Hayden, E. Bublick, THE LAW OF TORTS §464 (2d ed. 2015); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (1998) (no duty to warn of "obvious and generally known risks").

As both the Fourth Circuit and this Court have recognized, this principle applies to medical devices. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (manufacturer had duty to warn of risks that "were not well known to the medical community"); *Huskey v. Ethicon, Inc.*, 2015 WL 4944339 at *7 (S.D. W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about risks 'already known to the medical community.") (Illinois law). What is "well known" in the learned intermediary context, then, requires some assessment of what physicians already know.

The FDA device regulations which Dr. Pence purports to interpret are consistent with the common law and inconsistent with her view that the common knowledge of surgeons is "not relevant." They explicitly provide that information commonly known to the users need not be included in a device's labeling:

> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely . . . ***Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device***.

21 C.F.R. §801.109(c) (emphasis added); *see also* 21 C.F.R. §801.109(c); Ex. J, FDA Mar. 8, 1991 Device Labeling Guidance #G91-1 ("Provide frequency data from adequately reported clinical studies when the data is not well known to the device user . . . ."); *see also* J. Agar, *Labeling of Prescription Devices for the Food and Drug Administration and Product Liability: A Primer-Part I*, 45 Food Drug Cosm. L.J. 447, 455 (1990).

The Global Harmonization Task Force ("GHTF") guidelines Dr. Pence also cites do not contradict this principle of state and federal law even if they were competent to do that, which

they are not. She cites a document from the GHTF: "Label and Instructions for Use." But that document does not speak to the users' pre-existing knowledge of the risks one way or the other. *See* Ex. I, GHTF Label and Instructions for Use, Sept. 16, 2011.

Dr. Pence's failure to apply the correct legal standard for labeling is critical, because "[a]n expert opinion is inadmissible if based on incorrect legal standards." *Morley v. Square, Inc.*, 2016 WL 2733114, at *2 (E.D. Mo. May 11, 2016).[2] In order to opine about the sufficiency of a warning, a warnings expert must "have a sufficient basis for understanding what information is needed by a doctor in making his or her prescribing decision. Without knowing the baseline of what information is needed, it is not possible to opine meaningfully on the information's adequacy for that purpose." *Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept. 27, 2013) (excluding regulatory expert's opinion about sufficiency of warnings for a physician).

Further, it would be confusing and misleading for Dr. Pence to opine that Ethicon violated a standard that is different from the standard the jury will apply. *See* Fed. R. Evid. 403. As the Supreme Court has cautioned, "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 592-93.

For these reasons, Dr. Pence's warnings testimony should be excluded.

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[2] *See also Am. Med. Sys. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 900-901 (D. Minn. 2010) (excluding expert's testimony where she provided correct legal standard in expert report but did not apply it correctly); *In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert's opinion regarding adequacy of the warning because the incorrect standard applied by the expert "does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability"); *Carlson v. C.H. Robinson WW, Inc.*, 2005 WL 758601, at *4 (D. Minn. Mar. 30, 2005) (striking expert opinion that relied on more stringent standard than the applicable one, which "renders her conclusions unreliable").

2. Dr. Pence's reliance on GHTF guidelines is unreliable.

Dr. Pence's *post hoc* reliance on GHTF guidelines in an effort to have her opinions admitted in court reveals the unreliability of her opinions about the product warnings.

In her initial TVT, TVT-O, and Prolift reports, Dr. Pence did not cite GHTF guidelines. Rather, she only relied on FDA regulations. But after this Court's decisions in *Mathison* and other cases, she "included the GHTF information understanding instead of FDA regulations based on my understanding of the concerns about FDA sometimes being allowed, sometimes not being allowed, and that there are other standards on which to rely." Pence 3/9/16 Dep. at 28:7-11. Dr. Pence also submitted supplements to the TVT, TVT-O, and Prolift reports in which she states that her opinions were the same, but she added in a section saying she relied on GHTF guidelines. *See* Ex. D, C, B; *see also* Ex. K Pence Dep. 3/9/16 at 26:6-15 (agreeing she did not cite GHTF in support of Prolift opinions until supplemental report).

That Dr. Pence believes that the GHTF can merely be substituted for the FDCA without any impact on the opinions certainly calls her methodology into question. *See Claar v. Burlington N. R.R.*, 29 F.3d 499, 502-03 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method."). She has not performed a thorough analysis of GHTF guidelines and described how they apply here, but rather has merely erased FDA from her report and substituted GHTF in its place.

It further shows the litigation-driven nature of Dr. Pence's opinions that she has formed her opinions based on once source (FDA regulations) but then disposes of that source entirely when it would result in the exclusion of her testimony. Her opinions should be excluded.

3. Dr. Pence's opinion that Ethicon should have warned of the frequency or severity of risks is unsupported and unreliable.

For her opinion that the IFU should include information about the frequency or severity

of events, Dr. Pence relies on two objective sources: (1) the Blue Book Memo, and (2) the GHTF guidance. Ex. H Pence Dep. 3/24/16 Tr. 144:15-145:2.

The FDA Blue Book guidelines, however, only provide that such information should be included if not well known to the device user. Pence 3/24/16 Tr. 155:9-16. As described above, Dr. Pence has no basis to know what was already known about the device by the users of the device, pelvic floor surgeons, and incorrectly believes that information to be irrelevant. Further, to the extent she opines that the FDA Blue Book has been violated, that opinion by Dr. Pence is a legal conclusion that is improper and preempted. *See infra* Section II.F. In addition, this Court has ruled that it would violate Rule 403 for Dr. Pence to provide the jury with such expert testimony regarding FDA requirements. *See Winebarger v. Boston Scientific*, 2015 WL 1887222, *21 (S.D. W. Va. Apr. 24, 2015) (excluding Dr. Pence's opinions about deviations from FDA requirements).

In any event, the GHTF guidelines provide no further support for Dr. Pence's opinion that Ethicon should have warned of the frequency or severity of the risk. When asked to point to the specific part of the GHTF guidelines supporting her opinion, Dr. Pence could only point to Section 5.0's "general principles." Pence 3/24/16 Dep. at 142:21-142:5. [3]

In *Carlson v. Boston Scientific*, this Court observed that "[t]he GHTF document on product labels does not state – expressly or otherwise – that manufacturers should include the severity, frequency, and/or permanency of adverse event in a warnings, nor does it state that a label should qualify the difficulty of removing the device." *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *26 (S.D. W. Va. Apr. 28, 2015). The same is still true: Dr. Pence remains

[3] This section provides only that: "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling." Ex. I, GHTF Guidelines.

unable to point to any GHTF standard actually requiring this information in the IFU.

"As the Supreme Court has repeatedly held, 'nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'" *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)). Dr. Pence's opinion that the device labels should have included information about the frequency or severity of the risks is mere *ipse dixit* and should be excluded.

4. To the extent Dr. Pence is permitted to testify about warnings, she should not be permitted to opine that a device is "misbranded" or "adulterated."

Though in her most recent PROSIMA expert report Dr. Pence has abandoned the terms "misbranded" or "adulterated" (as well as reference to the FDA), they still appear throughout her earlier TVT, TVT-O, and Prolift reports. The terms "misbranded" or "adulterated" are legal conclusions: They have a "separate, distinct, and specialized meaning in the law" and improperly invade the province of the jury. *See United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002); *see also* 21 U.S.C. § 351 (defining "adulterated" devices); *id.* § 352 (defining "misbranded" devices). Thus, to the extent Dr. Pence is permitted to opine about the adequacy of the warnings, she should not be allowed to testify about "misbranding" or "adulteration."

C. Dr. Pence's opinions that Ethicon did not meet the post-market vigilance standard of care with respect to the TVT, TVT-O, and Prolift are inadmissible (TVT Report Opinion #4; TVT-O Report Opinion #5; Prolift Report Opinion #4).

Ethicon acknowledges the Court's prior rulings on this subject, but continues to maintain that Pence is not qualified to determine whether an adverse event should be reported to the FDA because she is not qualified to exercise medical judgment to examine issue reports and conclude the device is indeed related to the injury. *See, e.g.*, 28 C.F.R. § 802.20(c)(2); Fed. R. Evid. 702. Irrespective of her lack of qualifications, however, Dr. Pence's opinions about post-market

vigilance should be excluded for at least five independent reasons.

First, Dr. Pence's opinions about Ethicon's alleged failure to conduct post-market surveillance are unreliable because they are based solely on her review of the FDA's MAUDE database. The MAUDE database is not a reliable source for reaching scientific conclusions. The FDA itself warns users that the MAUDE data alone "cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *22 (S.D. W. Va. Apr. 24, 2015) (citing FDA's website). For this reason, this Court held that "application of the [MAUDE] data to reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community." *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *27 (S.D. W. Va. Apr. 28, 2015). This is consistent with the holding of courts around the country that anecdotal case reports are not reliable sources of information on which to base scientific conclusions.[4]

Second, even if the MAUDE database itself were a reliable source of information, Dr. Pence's review includes MDRs that ***cannot*** be used in this proceeding under federal law. Federal law requires that certain entities— "device user facilities" (*e.g.*, hospitals and other facilities not including physician's offices)—*must* report any time they learn a device "may have caused or contributed to a death" or serious injury. 21 U.S.C. § 360i(a)(1)(A) and (B). But federal law also requires that no such report "shall be admissible into evidence ***or otherwise used*** in any civil action." 21 U.S.C. § 360i(b)(3); *see also Lewis v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 14971, *15-17 (S.D. W. Va. Feb. 5, 2014) (acknowledging inadmissibility of such

[4] *See, e.g., Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 537 (W.D. Pa. 2003) ("[t]he great weight of authority squarely rejects the use of [adverse drug events] and case reports for the purpose of establishing general causation.") (citing cases).

reports under 21 U.S.C. § 360i(b)(3)). In her review, Dr. Pence did not exclude MDRs that were reported under 21 U.S.C. § 360i(a)(1)(A). Because federal law prohibits such reports to be "used" in "any civil action," the opinion is impermissible.

Third, evidence concerning whether or not Ethicon reported certain adverse events to the FDA is not helpful to the jury. The improper failure to report an adverse event to the FDA is nothing but a FDCA violation and has no bearing on liability here under state law. For this reason, among others, this Court has repeatedly excluded such opinions from Dr. Pence. In *Lewis v. Ethicon*, for example, the Court held that Dr. Pence's opinions about Ethicon's alleged failure to submit medical device reports to the FDA were inadmissible because "whether Ethicon . . . failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702." 2014 U.S. Dist. LEXIS 15351 at *2604; *see also United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").[5] So here, whether Ethicon met the post-market standard of care articulated by the FDA is irrelevant to the jury's determination of liability. Dr. Pence's opinion would do nothing but confuse the jury and should be excluded. *See* Fed. R. Evid. 403.

Fourth, any claim based on the failure to provide information to the FDA is preempted by *Buckman Co. v. Plaintiffs' Legal Comm*, 531 U.S. 341 (2001), as described in Section II.F, *infra*.

Finally, any opinion as to Ethicon's practices concerning MDRs are ultimately irrelevant because those practices cannot have affected the FDA's judgment. The FDA does not consider

[5] *See also Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989, at *36 (S.D. W. Va. Sept. 29, 2014) (excluding Dr. Pence's opinions about postmarket vigilance where "even if an explanation of BSC–FDA communications could shed light on the state law claims at issue, testimony on whether or not BSC complied with the FDCA would constitute an impermissible legal conclusion rather than an expert opinion."); *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *21 (S.D. W. Va. Apr. 24, 2015) (excluding Dr. Pence's opinions about violations of FDCA because, *inter alia*, "simply stating that BSC did not comply with FDA regulations is a legal conclusion, not an expert opinion").

MDR reporting to be fully informative. At the same time, in 2011 the FDA surveyed all the MDRs submitted by all mesh manufacturers and compared them to the scientific studies of vaginal mesh. It ultimately concluded that "[t]he long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA." FDA, Considerations About Mesh for SUI, April 2, 2013.[6]

D. The Court should exclude Dr. Pence's opinions that Ethicon did not properly test TVT-O, TVT, and PROSIMA (TVT-O Report Opinion #1; TVT Report Opinion #1; Prosima Report Opinion #2).

Dr. Pence is not qualified to render an opinion regarding what testing is required of the TVT, TVT-O, and PROSIMA device. What testing is "appropriate" for a medical device clearly involves both biomechanical engineering expertise and medical judgment taking into account various considerations such as the conditions to be treated and the risk profiles of the treatment options, expertise and experience which Dr. Pence does not have. *See* Fed. R. Evid. 702. However, Ethicon acknowledges the Court's prior rulings on this issue and submits the argument here to preserve the issue and raise additional reasons for exclusion..

In 2014, this Court found that Dr. Pence's opinion that additional testing should have been done on the devices "in [her] professional opinion" was inadequate to show reliable methodology. *See Lewis v. Ethicon*, 2014 WL 186872, *18 (S.D. W. Va. Jan. 14, 2014).

Since that time, Dr. Pence has finessed her reports to gerrymander the FDA out and the GHTF in—providing supplements to her reports to add a conclusory citation to GHTF guidelines as "additional foundation for [her] opinions." *See* Ex. F TVT/TVT-O Supplemental Report, p. 1; Ex. G Prolift/PROSIMA Supplemental Report, p. 1. In addition, in her February 2016 PROSIMA report, Dr. Pence states that "[f]or all medical devices, the internationally accepted

[6] *Available at* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm (last accessed Sept. 15, 2016).

standard of care is that a clinical evaluation of the device, including clinical data in the form of clinical studies, medical and scientific literature, and/or clinical experience must demonstrate that a favorable benefit-risk ratio exists for the device." Ex. E, PROSIMA Report, p. 34.

Nowhere in her reports, however, does Dr. Pence actually apply the GHTF guidelines—or any other objective standard for that matter—to the Ethicon data to determine that Ethicon's testing of the devices failed to meet those standards.

As Dr. Pence acknowledged in her recent deposition, the GHTF guidances do not necessarily require that the "clinical data" consist of clinical experiments involving humans with *that product*. Rather, Dr. Pence testified that under the GHTF guidance, "clinical data can be in the form of scientific medical literature and commercial experience as well as clinical studies." Pence 3/9/16 Dep. Tr. 75:8-11. She further testified that "the standards allows [a manufacturer] to evaluate the literature for similar devices or commercial experiences" and "[i]f the manufacturer can substantiate, based on the available information, that there's a favorable benefit-risk ratio, then premarket clinical studies may not be required." *Id.* at 76:3-4, 13-16.

This exposes an additional flaw in Dr. Pence's opinion, which is that she has not surveyed the body of clinical data in the medical literature and does not take into account either that literature or the FDA's 1988 placement of all surgical mesh in Class II based on its long history of safe and effective use. As a result, she cannot reliably say that Ethicon needed to do additional testing in light of that literature and those FDA findings. *See E.E.O.C. v. Freeman*, 778 F.3d 463, 469 ("courts have consistently excluded expert testimony that 'cherry-picks' relevant data"); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.").

In its Wave 1 ruling, the Court found Plaintiff did not respond to the argument that Dr. Pence did not apply the standards she cites. *In re: Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493685, at *3. But the Court reserved ruling because Plaintiffs stated Dr. Pence relied on her experience, and the Court had insufficient evidence to assess reliability. *Id.*

Dr. Pence's experience cannot make up for her failure to consider the relevant facts, i.e. pre-existing medical literature and FDA medical panel findings. And Plaintiff "has the burden to put forward evidence from which the court can determine that the proffered testimony is properly admissible under *Daubert*." *United States v. Crisp*, 324 F.3d 261, 273 (4th Cir. 2003) (citation and internal quotation marks omitted). Because the Plaintiff is unable to show the reliability of Dr. Pence's testing opinions, this Court should exclude them.

E. Dr. Pence's opinions that the TVT-O and PROSIMA labeling did not support adequate informed consent of patients are inadmissible (TVT-O Report Opinion #3; Prosima Report Opinion #4).

As described above, Dr. Pence is not qualified to opine about what warnings Ethicon should place on the product IFU. She is even further not qualified to opine about whether the IFUs are adequate for doctors to obtain informed consent of their patients. Dr. Pence is not a surgeon or a medical doctor and is therefore not in any position to know what surgeons know. She thus has no expertise regarding what additional information physicians need in order to adequately consent their patients. Her opinion should be excluded on this basis alone. *See* Fed. R. Evid. 702.

Further, Dr. Pence has applied no reliable methodology in order to understand the knowledge of the intended users of the product, pelvic floor surgeons. As described above, she erroneously claims this information is irrelevant to her opinions. *See* Section II.A.1.

In addition, this opinion assumes a duty that is inconsistent with the learned intermediary doctrine which requires Ethicon to warn doctors, not patients. It is the physician who decides

what the patient needs to be told to obtain informed consent, not the device manufacturer. If Ethicon has adequately warned the physician, its duty is at an end, and it would serve no purpose other than prejudice and confusion to recharacterize its duty as a duty to tell physicians what they should tell patients.

In its Wave 1 ruling, this Court reserved ruling on this issue "[b]ecause application of the informed consent doctrine turns on the applicable state law." *In re: Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493685, at *3. Ethicon agrees that the substantive informed consent law is state-specific. But no matter the legal standard, Dr. Pence has no expertise concerning the various legal standards for informed consent, nor has she reliably applied them. As the court in the *Diet Drugs* products liability litigation aptly observed:

> [T]o the extent that the doctrine of informed consent may be pertinent, it is measured by a legal standard. This standard varies among the numerous jurisdictions whose substantive law governs the individual cases in this MDL No. 1203. Dr. La Puma does not have the knowledge or expertise concerning the legal standard of informed consent as defined by each of these particular jurisdictions.

In re Diet Drugs, 2001 WL 454586, at *9 (E.D. Pa. Feb. 1, 2001); *see also Tyler v. Sterling Drug Co.*, 19 F. Supp. 2d 1239, 1245 (N.D. Okla. 1998) (finding plaintiffs had not shown "any general acceptance in the scientific or medical community that general concepts of informed consent equate to specific industry standards for warning labels"). So here, no matter the state's informed consent standard, Dr. Pence has no expertise concerning it, has not taken it into consideration in forming her opinions, and has thus not reliably applied it.

Finally, the Court did not previously consider Ethicon's argument that Dr. Pence's informed consent opinions are irrelevant. There are no informed consent claims at issue here, and whether or not a physician had adequate information to provide informed consent is

irrelevant. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citations omitted). What is at issue here is whether Ethicon adequately warned of the device's risks, and Dr. Pence has already covered that matter in her opinions concerning the adequacy of the labeling. The only additional element added by Dr. Pence's informed consent opinion is whether the physician could then use that information to convey it to his or her patients. Her testimony should be excluded.

F. Dr. Pence's opinion that Ethicon obtained clearance to market PROSIMA based on false or misleading statements to the FDA should be excluded (Prosima Report Opinion #1).

Dr. Pence seeks to tell the jury that the PROSIMA device was cleared based on false and misleading information and that it would not have been cleared had the FDA had Ethicon disclosed all the information it had. Ex. E PROSIMA Report, pp. 33-34. This information should be excluded for several reasons.

First, this opinion is no more than thinly veiled fraud on the FDA claim that is preempted under *Buckman*. In *Buckman*, the Supreme Court held that a state law cause of action claiming that a medical device manufacturer had committed "fraud on the FDA" by failing to disclose an intent to market a device for off-label use was "impliedly preempted" under the FDCA's regulatory scheme. *Id.* at 348. The Court reasoned that:

> The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: "[A]ll such proceedings for the enforcement, or to restrain violations, [under the FDCA] shall be by and in the name of the United States."

Id. at 349 n.4 (quoting 21 U.S.C. § 377(a)). The Court found that any claim that "exist[s] solely by virtue of the FDCA disclosure requirements" is preempted especially where the "existence of these federal enactments is a critical element in the[] case." *Id*. at 352-53.

It is the FDA's job to enforce the FDA regulatory scheme, not the job of courts in cases in which the FDA is not a party. Not only are Dr. Pence's opinions that the FDA acted on false or misleading information preempted, but they are also irrelevant legal conclusions. As this Court held in *Sanchez v. Boston Scientific Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *36 (S.D. W. Va. Sept. 29, 2014), "even if an explanation of BSC–FDA communications could shed light on the state law claims at issue, testimony on whether or not BSC complied with the FDCA would constitute an impermissible legal conclusion rather than an expert opinion."

Further, even if they were otherwise admissible, Dr. Pence's opinion that PROSIMA would not have been cleared by the FDA if the FDA had different or additional information is sheer speculation. Under *Daubert*, an expert's opinion must be based on "more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. If an expert "in formulating the ultimate opinion" makes "overreaching or speculative conclusions . . . based upon overreaching or speculative methodologies," "the expert['s] approaches are inconsistent with good science" and, thus, inadmissible. *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 839 (S.D. W. Va. 2011). The FDA in fact cleared Prosima and, even after the 2011 review, it did not order Ethicon to withdraw or stop selling Prosima. Instead, it asked for further testing. And the FDA's more recent order reclassifying vaginal mesh devices used to treat prolapse into Class III did not require that they be withdrawn. In fact, it expressly contemplated that they would continue to be sold.

Dr. Pence has no reliable basis to predict with any certainty what the FDA would have done with respect to PROSIMA's clearance had it had additional or different information apart from her personal opinion. *See United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014) (listing *Daubert* factors); *Winebarger v. Boston Scientific*, 2015 WL 1887222, *21 (S.D. W. Va.

Apr. 24, 2015) (observing that an expert "may not solely rely on his personal observations, especially when he seeks to provide broad opinions."). Her speculative prediction is not the sort of reliable scientific evidence passing scrutiny under *Daubert* and should be excluded.

G. The Court should exclude Dr. Pence's opinion that Ethicon did not act in the interest of patient safety when removing PROSIMA from the market (Prosima Report Opinion #5).

Dr. Pence claims that Ethicon should have acted more quickly to remove the PROSIMA from the market and violated its commitment to patient safety by failing to do so. Ex. E, PROSIMA Report, p. 48. In support of this opinion, Dr. Pence cites two sources: (1) her "professional opinion", and (2) the Johnson & Johnson Credo. This opinion is inadmissible and unsupported. In Wave 1, the Court excluded this opinion from Dr. Pence, finding that Dr. Pence's reliance on Ethicon's Credo was unreliable. *In re: Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4493685, at *3 ("Liability is not predicated on a company's compliance with its own credos or codes") (citing Restatement (Third) of Torts: Phys. & Emot. Harm. § 13 cmt. f (2010)). The same result is proper here.

First, Dr. Pence's opinion erroneously presumes that the decision to stop selling the device was safety-related. Further, neither Ethicon's nor Johnson & Johnson's internal standards are the legal standard by which the jury will determine liability. *See McHugh v. Jackson*, 2010 U.S. Dist. LEXIS 18827 at *6 n.4 (D. N.J. March 2, 2010) ("standard of care is not generally measured by provisions in internal guidelines…"). Finally, Dr. Pence is not qualified to opine about the Johnson & Johnson Credo. *See* Fed. R. Evid. 702. The opinion is unreliable, unhelpful to the jury, and should be excluded.

H. Dr. Pence's opinion that Prolift was misbranded or adulterated when it went on the market without clearance should be excluded (Prolift Report Opinion #1).

Dr. Pence opines that because Ethicon did not file a 510(k) application before marketing

the Prolift system it was misbranded and adulterated. Ex. B, Prolift Report at 62. This opinion is an improper legal conclusion founded solely on an FDCA violation.

At the time of the Prolift launch, Ethicon concluded that, based on the submission of its 510(k) for its GYNECARE GYNEMESH* PS device and its interpretation of the FDCA, federal regulations, and the FDA Guidance, Ethicon was not required to submit a new 510(k) notification for the Prolift System to FDA. In response to an FDA inquiry, Ethicon submitted a 510(k) application for Prolift on September 19, 2007. FDA cleared the Prolift System on May 15, 2008. It later determined that Ethicon had acted in good faith.

The purported duty to submit a 510(k) notification springs solely from FDCA regulations. Thus, Dr. Pence's opinion that Ethicon violated the standard of care by not submitting a 510(k) notification is nothing more than an opinion that Ethicon violated the FDCA. As this Court has observed, however, "expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the failure-to-warn claim than enlightenment." *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989, *35 (S.D. W. Va. Sept. 29, 2014); *see also Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("proffered evidence that has a greater potential to mislead than to enlighten should be excluded"). By the same token, "whether Ethicon . . . failed to furnish information to the FDA are not facts in issue in this case under Federal Rule of Evidence 702." *Lewis v. Ethicon*, 2014 U.S. Dist. LEXIS 15351 at *2604.

Dr. Pence's opinions about failure to submit a 510(k) notification have no relevance to this trial, are improper legal conclusions, and are preempted.

I. Dr. Pence's opinion that Ethicon reported false and misleading information to the FDA with respect to Prolift is improper (Prolift Report Opinion #2).

As with Dr. Pence's other opinions concerning violations of the FDCA and failure to

report certain things to the FDA, Dr. Pence's opinion that Ethicon "submitted false and misleading information to the FDA" should be excluded. *See* Prolift Report, p. 106.

The FDA is the only entity in a position to determine whether it has been misled. For this reason, the court in *In re Trasylol Products Liability Litigation*, 763 F. Supp. 2d 1312 (S.D. Fla. 2010), held that evidence of what information was or was not given to the FDA is only relevant to a fraud on the FDA claim, which is preempted by *Buckman*. The court stated:

> [E]vidence or testimony that Bayer failed to adequately or timely provide information to the FDA pursuant to FDA reporting obligations that run to the FDA . . . is generally irrelevant to Plaintiffs' state-law claims and thus inadmissible. Such evidence or testimony would instead be relevant to a fraud-on-the-FDA claim that is preempted by *Buckman*. . . . The duty at issue in this regulation is a duty to disclose to the FDA, not a duty that is owed to the Plaintiffs or their prescribing physicians.

Id. at 1329-30. So here, any opinion that Ethicon submitted false and misleading information to the FDA is preempted; is an irrelevant legal opinion; and is irrelevant to the jury's determination of liability. The FDA has conducted an extensive post-2008 review of pelvic mesh devices and it has not accused Ethicon of misleading it about Prolift. This opinion should therefore be excluded under Fed. R. Evid. 401 and 403.

J. Dr. Pence should not be permitted to testify regarding Gynemesh PS, Prolene, or TVT-Secur.

Dr. Pence has been designated as an expert in a number of cases involving the Gynemesh PS, Prolene, and TVT-Secur products. *See* Ex. A. However, she has not provided expert reports for those products—only for TVT, TVT-O, Prolift, and PROSIMA. She should not be permitted to offer opinions regarding Gynemesh PS, Prolene, or TVT-Secur under Fed. R. Civ. P. 26.

III. CONCLUSION

For these reasons, Ethicon respectfully requests that Dr. Pence's testimony be excluded in the entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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